

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION  
DECISION SUMMARY FOR  
ASSAY AND INSTRUMENT TEMPLATE**

**A. 510(k) Number:**

k111890

**B. Purpose for Submission:**

Clearance of new devices

**C. Measurand:**

Capillary whole blood glucose from the finger

**D. Type of Test:**

Whole blood glucose concentration through a quantitative amperometric assay (GDH-FAD)

**E. Applicant:**

Taidoc Technology Corporation

**F. Proprietary and Established Names:**

FORA Diamond Prima Blood Glucose Monitoring System  
FORA Diamond Mini Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR: 862.1345, Blood Glucose Test System

2. Classification:

Class II

3. Product code:

NBW, LFR

4. Panel:

75 (clinical chemistry)

**H. Intended Use:**

1. Intended use(s):

See Indications for Use

2. Indication(s) for use:

**FORA Diamond Prima Blood Glucose Monitoring System:**

FORA Diamond Prima Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The system is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

This system is intended for single-patient use and should not be shared.

The FORA Diamond Prima Blood Glucose Test Strips are for use with the FORA Diamond Prima Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

**FORA Diamond Mini Blood Glucose Monitoring System:**

FORA Diamond Mini Blood Glucose Monitoring System is intended for self testing outside the body (*in vitro* diagnostic use) in the quantitative measurement of glucose in fresh capillary whole blood from the finger. The system is intended for use by people with diabetes mellitus at home as an aid in monitoring the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

This system is intended for single-patient use and should not be shared.

The FORA Diamond Mini Blood Glucose Test Strips are for use with the FORA Diamond Mini Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips.

3. Special conditions for use statement(s):

- For single person, over the counter use
- Not for use in the screening or diagnosis of diabetes
- Not for use in testing neonates
- Not for use on critically ill patients, dehydrated patients, patients in shock

- or hyperosmolar patients
- Not for alternative site testing

4. Special instrument requirements:

The FORA Diamond Prima Blood Glucose Test Strips are must be used with the FORA Diamond Prima Blood Glucose Meter and the FORA Diamond Mini Blood Glucose Test Strips must be used with the FORA Diamond Mini Blood Glucose Meter.

**I. Device Description:**

FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System consist of three main components: the meter, test strips and control solutions. These products have been designed, tested, and proven to work together as a system to produce accurate blood glucose test results. Use only FORA test strips and FORA control solutions (cleared under k093724) with the FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System.

The blood glucose detection method and measurement is by an electrochemical biosensor technology using FAD-dependent glucose dehydrogenase (FAD-GDH).

The two blood glucose systems have the same technical components although the FORA Diamond Mini Blood Glucose is smaller in size and does not have the test strip ejector, ketone warning function and does not have the capacity to perform daily averaging of measurements. However, they use the same test strips.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

TD-4277 blood glucose monitoring system

2. Predicate 510(k) number(s):

k100322

3. Comparison with predicate:

Item	TD-4277 Blood Glucose Monitoring System - Predicate	FORA Diamond Prima Blood Glucose Monitoring System	FORA Diamond Mini Blood Glucose Monitoring System
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Intended Use/Indications for Use	It is intended to be used for quantitative measurement of glucose in fresh capillary whole blood as an aid to monitor the effectiveness of diabetes control in people with diabetes.	Same	Same
Sample test time	5 seconds	Same	Same
Detection method	Amperometry	Same	Same
Enzyme	Glucose dehydrogenase	Same	Same
Calibration Coding	No-coding: Code number is preinstalled and only one code number is assigned. User must choose and insert the correct test trip.	Same	Same
Memory	1000 measurements	450 measurements	450 measurements
Test range	20-600 mg/dL	Same	Same
Hematocrit range	20-60%	Same	Same
Sample type	Fresh capillary and venous whole blood	Fresh capillary whole blood	Fresh capillary whole blood
Sample sites	Fingertip	Same	Same
Sample volume	0.5 uL	Same	Same

**K. Standard/Guidance Document Referenced (if applicable):**

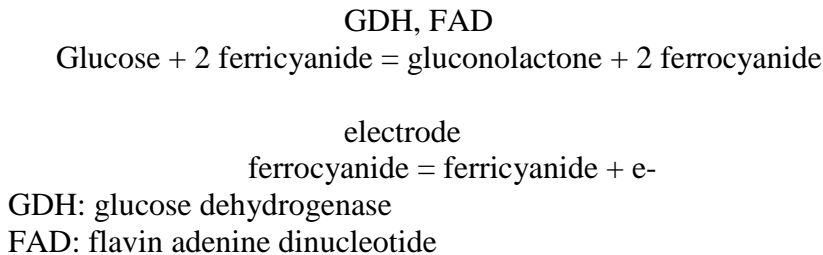
- ISO 14971:2007. Medical devices-Application of risk management to medical devices.
- ISO 15197. *In vitro* diagnostic test systems. Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- EN 60601-1-1. Medical electrical equipment, Part 1-1. General requirements for safety. Safety requirements for medical electrical systems.
- EN 60601-1-2:2001 (A1:2006). Medical electrical equipment, Part 1-2. General requirements for basic safety and essential performance. Electromagnetic Compatibility.
- EN 61326-1:2006. Electrical equipment for measurement, control, and laboratory

- use. EMC Requirements. General requirements.
- IEC/EN 61010-2-101:2002. Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 2-101. Particular requirements for *in vitro* diagnostic (IVD) medical equipment.

#### **L. Test Principle:**

FORA Diamond Prima and FORA Diamond Mini Blood Glucose meters, in conjunction with the same test strips, utilize amperometric technology to quantitatively measure the glucose concentration in whole blood samples and in control solutions. A glucose dehydrogenase sensor based on the carbon electrode adopting the amperometric assay utilizes the enzyme glucose dehydrogenase to catalyze the formation of gluconolactone from the oxidation of glucose whereby two electrons are produced. Through the mechanism of the mediator, electrical current is generated and it is proportional to the quantity of glucose in the sample.

The reaction principle of reagent depends on following reaction equation:



The glucose biosensors recognize the glucose present in whole blood or control solutions by virtue of the specificity of the enzyme FAD dependent glucose dehydrogenase (GDH) present on the test strip. The electrons liberated by this reaction are transferred via a co-factor and mediator to the meter where they are read as a small electrical current. The magnitude of the resultant current is proportional to the concentration of glucose in the specimen and the signal is converted into a readout displayed on the meter.

#### **M. Performance Characteristics (if/when applicable):**

##### **1. Analytical performance:**

##### ***a. Precision/Reproducibility:***

The sponsor performed precision studies in accordance with ISO 15197 and CLSI EP-5A. Fresh venous whole blood adjusted to 5 glucose levels (hematocrit 45%) were used for within-day precision studies. Each concentration was tested 10 times on 10 meters, using 3 test strip lots, (100 total tests divided between 3 strip lots per blood glucose level). Results for each meter are summarized below:

Results of repeatability precision of FORA Diamond Prima

	Interval 1 (30-50 mg/dL)			Interval 2 (51-110 mg/dL)			Interval 3(111-150 mg/dL)		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	43.2	42.7	42.0	86.0	84.9	85.5	138.3	135.9	137.3
SD	1.51	1.53	1.60	2.95	2.98	2.89	4.81	4.37	4.43
CV	3.50%	3.58%	3.82%	3.44%	3.50%	3.38%	3.48%	3.21%	3.22%
<b>Overall mean</b>		42.6			85.5			137.2	
<b>SD</b>		1.62			2.94			4.58	
<b>CV</b>		3.81%			3.43%			3.34%	

	Interval 4 (151-250mg/dL)			Interval 5 (251-400 mg/dL)		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	225.1	223.0	219.7	358.6	363.4	364.2
SD	7.30	6.67	6.61	10.86	10.77	11.21
CV	3.24%	2.99%	3.01%	3.03%	2.96%	3.08%
<b>Overall mean</b>		222.3			362.3	
<b>SD</b>		7.15			11.14	
<b>CV</b>		3.22%			3.07%	

Results of repeatability precision of FORA Diamond Mini

	Interval 1 (30-50 mg/dL)			Interval 2 (51-110 mg/dL)			Interval 3(111-150 mg/dL)		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	41.9	41.5	41.1	76.0	75.0	75.8	122.6	121.8	123.2
SD	1.61	1.54	1.43	2.51	2.25	2.25	3.94	3.86	3.80
CV	3.84%	3.72%	3.48%	3.30%	3.00%	2.97%	3.21%	3.17%	3.08%
<b>Overall mean</b>		41.4			75.6			122.6	
<b>SD</b>		1.54			2.35			3.86	
<b>CV</b>		3.72%			3.10%			3.15%	

Table 3. (continued). Results of repeatability precision of FORA Diamond Mini

	<b>Interval 4 (151-250mg/dL)</b>			<b>Interval 5 (251-400 mg/dL)</b>		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	203.9	204.1	203.0	332.2	333.4	332.0
SD	6.60	5.98	6.26	10.41	10.19	10.58
CV	3.24%	2.93%	3.08%	3.13%	3.06%	3.19%
<b>Overall mean</b>		203.6			332.5	
<b>SD</b>		6.24			10.33	
<b>CV</b>		3.06%			3.11%	

In addition to the study above, the sponsor also evaluated day-to-day precision using control samples with 3 different levels of glucose. Three lots of test strips and 10 meters were used in the study, with 1 test performed on each meter per day for 10 days, (100 total tests divided between 3 strip lots per control level). The results for both meters are summarized below

Results of intermediate precision of FORA Diamond Prima

<b>Control solution levels</b>	<b>Low (30-50 mg/dL)</b>			<b>Normal (96-144 mg/dL)</b>			<b>High (280-420 mg/dL)</b>		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	42.1	41.5	42.2	111.8	114.0	112.1	367.1	377.0	359.4
SD	1.78	1.70	1.74	4.09	3.99	4.04	12.58	14.19	12.50
CV	4.22%	4.08%	4.12%	3.66%	3.50%	3.61%	3.43%	3.76%	3.48%
<b>Overall mean</b>		42.0			112.6			367.0	
<b>SD</b>		1.74			4.11			14.84	
<b>CV</b>		4.15%			3.65%			4.04%	

Results of intermediate precision of FORA Diamond Mini

<b>Control solution levels</b>	<b>Low (30-50 mg/dL)</b>			<b>Normal (96-144 mg/dL)</b>			<b>High (280-420 mg/dL)</b>		
Lot	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804	PR110113	TR100716	TR100804
Mean	44.0	43.6	44.2	122.7	122.9	123.1	338.8	330.1	338.1

SD	1.65	1.70	1.62	4.30	4.03	4.26	12.07	12.19	11.70
CV	3.75%	3.89%	3.66%	3.51%	3.28%	3.46%	3.56%	3.69%	3.46%
<b>Overall mean</b>	43.9			122.9			335.9		
<b>SD</b>	1.65			4.16			12.44		
<b>CV</b>	3.76%			3.39%			3.70%		

*b. Linearity/assay reportable range:*

The sponsor performed linearity studies using adjusted venous blood samples with 10 different glucose concentrations ranging from 10-20, 21-50, 51-80, 81-120, 121-200, 201-300, 301-400, 401-500, 501-600 and 601 - 700 mg/dL for the FORA Diamond Prima Blood Glucose and FORA Diamond Mini Blood Glucose Monitoring System. For each concentration, 10 consecutive tests (with 5 measurements per lot) by YSI-2300 and FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System respectively. The resulting data was compared and the linear regression analyses were as follows:

FORA Diamond Prima Blood Glucose Monitoring System

	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R <sup>2</sup>
Lot 1	1.0110	0.9983 - 1.0237	0.1371	-4.2103 - 4.4845	0.9981
Lot 2	1.0036	0.9900 - 1.0172	0.2676	-4.3760 - 4.9112	0.9978
Lot 3	1.0142	1.0012 - 1.0272	-1.5864	-6.0285 - 2.8557	0.9981

FORA Diamond Mini Blood Glucose Monitoring System

	Slope	Slope 95% CI	Intercept	Intercept 95% CI	R <sup>2</sup>
Lot 1	1.0127	0.9992 - 1.0262	0.7012	-3.9170 - 5.3194	0.9979
Lot 2	1.0009	0.9905 - 1.0114	-2.3044	-5.8797 - 1.2709	0.9987
Lot 3	1.0113	0.9967 - 1.0259	2.4061	-2.5886 - 7.4008	0.9975

The measuring range of 20-600 mg/dL for both Blood Glucose Monitoring Systems and have been shown to be linear.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Test strips have been cleared under predicate k100322

d. *Detection limit:*

See linearity study

e. *Analytical specificity:*

The following protocol was applied to both FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System respectively.

The sponsor indicated that the interference study protocol was developed according to CLSI EP 7-A2. Venous blood was obtained from fasting subjects and collected in a heparin-Na (sodium heparin) vacutainer tube (Hct around 45%). Two concentrations of glucose were adjusted to 70 mg/dL (low) and 150 mg/dL (high) using the YSI 2300 as a reference instrument. The glucose samples were spiked with the potentially interfering compounds equivalent to the highest therapeutic dosage and toxic level (or ten times the highest therapeutic concentrations when toxic levels were not known), and tested on 3 lots of test strips. Bias was calculated as the mean percent difference in glucose reading between the test and control concentration groups. All samples tested showed % bias within  $\pm 10\%$  between the test and the control groups. For both FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System, the sponsor claims no significant interference ( $\leq 10\%$  difference) for the substances and concentrations shown in the table below:

Substance	Therapeutic / Physiologic Concentration Range (or Upper Limit) (mg/dL)	Concentration Tested (mg/dL)	Diamond Prima/Diamond mini
Acetylsalicylic Acid	2 - 10	50	No interference
Acyclovir	0.23 - 0.31	3.1	No interference
Allopurinol	0.5	5	No interference
Amitriptylline	0.012 - 0.025	0.25	No interference
Amoxicillin	0.55 - 1.1	11	No interference
Ampicillin	0.5	5	No interference
Aspirin (Salicylic Acid)	10 - 30	60	No interference
Atenolol	0.1 - 0.2	10	No interference
Bicarbonate	244 (29 mM)	336 (40 mM)	No interference
Bile Acids (Cholic Acid)	0.7	6	No interference

Caffeine	0.3 - 1.5	10	No interference
Calcium	2.8 mM	5 mM	No interference
Chloride	108 mM	140 mM	No interference
Cholesterol	300	500	No interference
Clonidine	0.0001 - 0.0002	2	No interference
Creatinine	1.7	30	No interference
Digoxin	0.0001 - 0.00025	0.16	No interference
Diphenhydramine	0.01 - 0.1	1	No interference
K2EDTA	180	702	No interference
K3EDTA	175.5	702	No interference
Enalapril	0.012 - 0.015	0.15	No interference
Ephedrine HCl	1.8	50	No interference
Erythromycin	0.2 - 2.0	20	No interference
Estrone	0.0011	0.1	No interference
Famotidine	0.008 - 0.013	0.13	No interference
Fluoxetine	0.08	0.8	No interference
Fructose	7.5	1000	No interference
Furosemide	0.1 - 0.3	2	No interference
Galactose	< 5	1000	No interference
Gentisic Acid	0.2 - 0.6	2	No interference
Glyburide	0.018 - 0.025	1.07	No interference
Hemoglobin	2.5	500	No interference
Heparin (Li)	35 - 100 U/dL	6800 U/dL	No interference
Heparin (Na)	35 - 100 U/dL	6800 U/dL	No interference
Ibuprofen	1 - 7	55	No interference
Isomalt	N/A	1000	No interference
Lactose	< 0.5	1000	No interference
Lactitol	N/A	1000	No interference
Lidocaine	0.15 - 0.6	6	No interference
Lipemic Samples (Triglycerides)	3000	30 - 300	No interference
Magnesium	1.1 mM	5 mM	No interference
Maltitol	N/A	1000	No interference
Maltose	N/A	1000	No interference
Metaproterenol	0.00022 - 0.00130	1.81	No interference
Metformin HCl	0.5 - 4	50	No interference
Metoprolol	0.005 - 0.027	0.3	No interference
Naproxen	3-12	100	No interference

Nifedipine	0.017	0.17	No interference
Nortriptyline	0.005 - 0.015	0.15	No interference
Penicillin	1.2	12	No interference
pH	7.35 - 7.45	6.7 - 9.8	No interference
Phenytoin	1 - 2	10	No interference
Piroxicam	0.3-0.5	5	No interference
Potassium	5.9 mM	10 mM	No interference
Sodium	135 - 145 mM	200 mM	No interference
Sorbitol	0.044	1000	No interference
Sulfamethoxazole	5-12	120	No interference
Sulfate	1 mM	5 mM	No interference
Terfenadine	0.00015 - 0.00045	0.45	No interference
Tetracycline	0.4	10	No interference
Theophylline	1.0 - 2.0	25	No interference
Tolbutamide	4.32 - 24	64	No interference
Total Protein (gamma-Globulin)	6000 - 8000	12000	No interference
Xylitol	N/A	1000	No interference
Urea	38	600	No interference
Vancomycin	0.025	25	No interference
Verapamil	0.014 - 0.045	0.45	No interference
Vitamin E	0.5 - 2.0	20	No interference
Warfarin	0.1 - 1.0	2	No interference

For both FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System the summary of drugs and concentrations in excess of  $\pm 10\%$  bias is as follows:

Substance	Limiting Concentration (mg/dL)	Therapeutic / Physiologic Concentration Range (or Upper Limit ) (mg/dL)
Acetaminophen	> 5	0.45 - 3
L-Dopa	> 0.7	0.02 - 0.28
Methyl-Dopa	> 0.625	0.1 - 0.5
Tolazamide	> 6.25	1.6
Mannose	> 250	1.15
Dopamine	> 1.25	0.03
Xylose	> 6.25	N/A
Pralidoxime Iodide	> 5	N/A

The sponsor has the following limitations in their labeling of both FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System:

Xylose : Do not test blood glucose during or soon after an absorption test. Xylose can give falsely elevated results.

There is no significant interference ( $\leq 10\%$ ) in the presence of galactose, maltose, fructose or mannitol observed in blood glucose tests as demonstrated in studies up to 1,000 mg/dL

Lipemic Effects: Blood triglycerides up to 2000 mg/dL (22.8 mmol/L) do not affect the results significantly ( $\leq 10\%$ ), but may affect results at higher levels.

*f. Assay cut-off:*

Not applicable

## 2. Comparison studies:

### *a. Method comparison with predicate device:*

The sponsor conducted an accuracy study at three hospital sites. Trained professionals obtained 180 samples from diabetic and non-diabetic outpatient participants. The range of glucose values tested was 37-503 mg/dL for Diamond Prima and 37~493 mg/dL for Diamond Mini BGMS. In order to obtain sufficient samples in the lowest and highest concentration intervals, 12 venous samples were obtained and either allowed to glycolyze to obtain low values or spiked with additional glucose. Samples that were  $<50$  mg/dL and  $>400$  mg/dL were contrived samples and samples between 50 to 440 mg/dL were natural capillary samples from the fingertip.

Accuracy results for glucose concentration  $< 75$  mg/dL

	Within $\pm 5$ mg/dL	Within $\pm 10$ mg/dL	Within $\pm 15$ mg/dL
Diamond Prima	15 / 20 (75.0 %)	20 / 20 (100 %)	20 / 20 (100 %)
Diamond Mini	15 / 20 (75.0 %)	20 / 20 (100 %)	20 / 20 (100 %)

Accuracy results for glucose concentration  $\geq 75$  mg/dL

	Within $\pm 5$ %	Within $\pm 10$ %	Within $\pm 15$ %	Within $\pm 20$ %
Diamond Prima	86 /160 (53.7 %)	146 /160 (91.0 %)	157 /160 (98.0 %)	160 /160 (100 %)
Diamond	71 /160 (44.3 %)	148 /160 (92.5 %)	158 /160 (99.0 %)	160 /160 (100 %)

Mini	%)	%)	%)	%)
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Linear regression for Diamond Prima (n= 180) is as follows:

$$(y = 0.9766x + 5.7464, R^2 = 0.9785)$$

Linear regression for Diamond Mini (n= 180) is as follows:

$$(y = 0.9715x + 6.0535, R^2 = 0.9823)$$

*b. Matrix comparison:*

Not applicable. Capillary whole blood is the only indicated sample matrix.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable

*b. Clinical specificity:*

Not applicable

*c. Other clinical supportive data (when a. and b. are not applicable):*

Consumer study:

A study was conducted to demonstrate that untrained lay users can correctly perform a glucose test using the DIAMOND Prima and DIAMOND Mini Blood Glucose Monitoring Systems and obtain accurate results. In all, 184 male and female subjects of varying demographics were recruited. Each subject was asked to perform a self test using only the provided English language labeling. A venous blood specimen from each subject was also obtained by a healthcare professional and tested on the YSI reference method. The results are summarized in the tables below.

Difference distribution for glucose concentration <75mg/dL of lay users versus YSI-2300

	Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15mg/dL
DIAMOND Prima	12/23 (52.2 %)	22/23 (95.7 %)	23/23 (100 %)
DIAMOND Mini	14/23 (60.9 %)	21/23 (91.3 %)	23/23 (100 %)

Difference distribution for glucose concentration ≥ 75mg/dL

	Within $\pm$ 5 %	Within $\pm$ 10 %	Within $\pm$ 15 %	Within $\pm$ 20 %
DIAMOND Prima	87/161 (54.0 %)	137/161 (85.1 %)	155/161 (96.3 %)	161/161 (100 %)
DIAMOND Mini	72/161 (44.7 %)	127/161 (78.9 %)	157/161 (97.5 %)	161/161 (100 %)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Time of day	Normal plasma glucose range for people without diabetes
Fasting and before meal	Less than 100 mg/dL (5.6 mmol/L)
2 hours after meals	Less than 140 mg/dL (7.8 mmol/L)

Source: American Diabetes Association (2010). Clinical Practice Recommendations. Diabetes Care, 33 (Supplement 1): S1-100.

**N. Instrument Name:**

FORA Diamond Prima Blood Glucose Meter and  
FORA Diamond Mini Blood Glucose Meter

**O. ~~System~~ Descriptions:**

1. Modes of Operation:

Each test strip is single use and requires 0.5 uL sample volume of capillary blood. Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

Yes \_\_\_\_\_ or No X

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No \_\_\_\_\_

4. Specimen Sampling and Handling:

This device is intended to be used with capillary whole blood from the finger only. The whole blood sample is applied directly to the test strip.

5. Calibration:

The calibration code for the vial of test strips should be selected or verified by the user from the available choices of code numbers programmed in the meter. Users are instructed where to find the calibration code information on the test strip vial label.

6. Quality Control:

The sponsor states that the system can be used only with FORA control solutions

(cleared under k093724). Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges

**P. Other Supportive Device and Instrument Information:**

1. Hematocrit Study

The effect of different hematocrit levels was evaluated with one test strip lot and 10 FORA Diamond Prima Blood Glucose meters and 10 FORA Diamond Mini Blood Glucose Monitoring meters respectively. In both cases, blood samples at six glucose concentrations (20-30, 50-80, 100-150, 200-250, 350-400 and 550-600 mg/dL) were analyzed. The glucose samples were prepared from venous blood at 10 different hematocrit levels (20, 25, 30, 35, 40, 45, 50, 55, 60 and 65%). Glucose results for each concentration and hematocrit level were compared to samples tested on the YSI reference method.

The data supports the sponsor's claim that hematocrit in the range of 20%-60% does not significantly interfere (more than  $\pm 15\%$ ) with glucose measurements using both test system.

2. Altitude:

A study was conducted to evaluate the effect of altitude up to 15,000 feet on performance of the FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System using a glove box system which simulates 4 elevations from sea level to 15,000 feet (4500 meters). Venous whole blood samples at five glucose concentrations ranging from 50-600 mg/dL were tested at four altitudes using three lots of test strips and 4 FORA Diamond Prima Blood Glucose meters and FORA Diamond Mini Blood Glucose meters respectively. Each sample was also evaluated by the YSI method. At altitudes up to 15,000 feet, test results were within  $\pm 10\%$  of YSI values for both meters.

3. Test system operating conditions:

Studies were performed using four FORA Diamond Prima Blood Glucose meters and four FORA Diamond Mini Blood Glucose meters respectively with three lots of test strips, and three venous whole blood samples with glucose concentrations of 64.2, 124 and 318 mg/dL. Testing was performed at various conditions in the claimed conditions 50-104°F (10-40°C) and at a relative humidity from 20-85% and results compared to the reference YSI. There were no significant differences in glucose concentrations across the temperature and humidity ranges tested. Results demonstrated that the test system can be used at temperatures from 50-104°F (10-40°C) and at a relative humidity from 20-85%.

4. User performance study:

For the user performance study summarized under consumer study above, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.

4. Readability assessment:

The sponsor performed a readability assessment of the labeling and states that the user manual, strip insert, and control insert are written at 8th grade level or below based on SMOG analysis.

5. EMC testing

EMC testing was evaluated and certified by Electronics Testing Center Taiwan and a letter of attestation was issued and attached to file.

6. Sample volume study

A sample volume study was performed to verify the test strip sample volume requirement of 0.5 µL for both FORA Diamond Prima Blood Glucose Monitoring System and FORA Diamond Mini Blood Glucose Monitoring System. Three samples with glucose concentrations approximately 50, 150, and 350 mg/dL were evaluated with three lots of test strips with 5 different FORA Diamond Prima and FORA Diamond Mini meters respectively. Each of the three blood samples was applied to the strips at sample volumes 0.4, to 1.5 µL. Protocols and acceptance criteria were provided and found to be acceptable. The sponsor concluded that sample volumes  $\geq 0.5$  µL produced accurate results and sample volumes  $< 0.5$  µL produced inaccurate results for both meters. The labeling provides instructions and graphics to assist the user in obtaining and applying an adequate sample volume in both cases.

7. Infection Control

The devices are intended for single-patient use only. Disinfection studies were performed on these meters by an outside commercial testing company to determine the robustness of the meter to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of blood borne pathogens, particularly Duck hepatitis B virus (HBV). Micro-Kill Plus™ disposable wipes (EPA Reg. No: 59894-10-37549) were validated, demonstrating complete inactivation of live virus for use with the meter. The sponsor also demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 5,000 cleaning and disinfection cycles designed to simulate 5 years of use by lay users. Labeling has been reviewed for adequate instructions in validated cleaning and disinfection procedures.

8. Software validation

Software validation verification has been reviewed and the information the sponsor provided was deemed to be sufficient.

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.